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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/691,782      | 10/23/2003  | Thomas W. Adkins     | PRD-55NP            | 7159             |

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EXAMINER

DENTZ, BERNARD I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/691,782

Applicant(s)

ADKINS ET AL.

Examiner

Bernard Dentz

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-9-2005</u> . | 6) <input type="checkbox"/> Other: ____.  |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Process claims 1-5, 7-10, 12-16, 26-30, 32-35 and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Maryanoff et al, US Patent 5,387,700 cited by applicants. It discloses the instant 2-step process of making the sulfamates of the instant tetrahydropyran methanol and cyclohexane methanol derivatives. The solvents for each of the 2-steps are the same as applicants. See t-butyl methyl ether or tetrahydrofuran used as solvents in the reaction of the above methanol derivatives with sulfuryl chloride in the presence of a base such as pyridine to produce the chlorosulfate intermediate and again used in the second step wherein the chlorosulfate is reacted with amine. See col. 2-5. Applicants' process does not differ from this in that it is specified as being continuous. Firstly "continuous" takes in all kinds of gradations of "continuity". The reference does its reactions over time. In that sense it is continuous.

Claims 22-25 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Maryanoff et al, supra This patent produces the same compounds as made in the instant case as explained above. Product-by-process claims are construed as being product claims. In chemistry compounds no matter by which process they are

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produced are the same. At col. 1, lines 30-47 said compounds are disclosed as possessing "anticonvulsant activity and thus are useful in the treatment of conditions such as epilepsy". Thus pharmaceutical composition claims 23-25 and 49-51 are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Process claims 1-21 and 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maryanoff et al, supra. Claims 1-5, 7-10, 12-16, 26-30, 32-35 and 37-41, the claims rejected above as being anticipated can be argued to differ from the reference because of the recitation of "continuous". However of course it is obvious that it is desirable to make the process as continuous as possible and this expedient is considered to be obvious to one of ordinary skill in the art. See In re Dilnot 138 USPQ 248. The recitation of glyme, i.e. ethylene glycol dimethyl ether, as solvent in claims 6, 11, 31 and 36 is considered to be obvious since it is an ether closely related to the ethers recited as solvents by Maryanoff et al. The recitation in claims 17-20 and 42-45 of removing solvent and "volatiles" is of course a standard means of purification. The recitation of running both steps in a "continuous stirred tank reactor" of course is just standard chemical procedure in synthesizing large amounts of chemicals.

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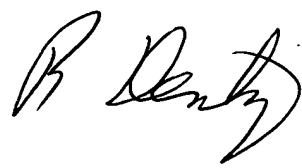
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

6-1-2005



BERNARD DENTZ  
PRIMARY EXAMINER  
GROUP 1000